K083115

510(k) Notification Submission – Special 510(k)
Modification to Intel® Health Guide PHS6000

510(k) Summary
As required by 21 CFR §807.92(c)

NOV 2 6 2008

Submitter

510(k) Owner:	Intel Corporation
Address:	1900 Prairie City Road, FM7-197, Folsom, CA 95630
Telephone:	(408) 765-2060
Contact Person:	Tae-Woong Koo
Date Prepared:	October 20, 2008

Device Information

Trade Name:	Modification to Intel® Health Guide PHS6000
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following device:
Intel Corporation's Intel® Health Guide PHS6000 (**K080798**)

Device Description

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

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The Intel® Health Guide PHS6000 system consists of the:

(1) Intel® Health Guide PHS6000 hardware:

The physical component of the Intel® Health Guide PHS6000 is an electronic device contained in a plastic enclosure with a touch screen, video camera with privacy screen, microphones, speakers and a reminder light which is mounted into the top of the case. On the back of the device is a power socket, a headphone socket, a Broadband (high-speed) internet socket for connection to a broadband network. The device has medical device sockets for connection to specific physiological monitors, and may optionally have a phone socket for modem connection to a standard phone line.

(2) Intel® Health Guide software application:

The software application captures, stores, and transmits information to a secure website via a standard telephone line or a LAN/WAN connection.

(3) Intel® Care Management Suite software application:

The application allows caregivers to review patient vital signs on the secure website. The Intel® Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

(4) Processor software application:

The processor software application manages the interface between the Intel® Health Guide PHS6000 software application and the secure website.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The device is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

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Indications for Use

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

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Technological Characteristics

The Intel® Health Guide PHS6000 is substantially equivalent to the predicate device in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source, and display method.

Safety and Efficacy

The Intel® Health Guide PHS6000 does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2008

Intel Corporation
c/o Mr. Tae-Woong Koo, Ph.D.
Manager of Medical Regulatory Affairs
Digital Health Group
1900 Prairie City Road, FM7-197
Folsom, CA 95630

Re: K083115
Trade/Device Name: Intel® Health Guide PHS6000
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiological Signal Radiofrequency Transmitters and Receivers
Regulatory Class: Class II
Product Codes: DRG, LFR, CGA
Dated: November 18, 2008
Received: November 20, 2008

Dear Dr. Koo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

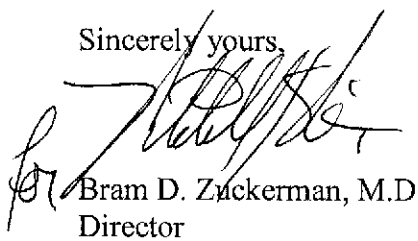
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number: K083115

Device Name: Modification to Intel® Health Guide PHS6000

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 11/26/08
Division of Cardiovascular Devices

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